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FDA Finalizes PCCP Guidance for AI-Enabled Medical Devices

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Today FDA issued final guidance to provide recommendations for predetermined change control plans (PCCPs) tailored to artificial intelligence (AI) enabled device software functions. FDA recognizes that development of AI-enabled devices is an iterative process, and PCCPs are intended to allow developers to plan for modifications, while continuing to provide a reasonable assurance of safety and effectiveness. FDA provides that a PCCP should include planned modifications, a methodology to develop, validate and implement those modifications, and an assessment of an impact of those modifications. FDA initially introduced the concept of PCCPs in a 2019 white paper, and the Food and Drug Omnibus Reform Act of 2022 created provisions regarding PCCPs. For example, a supplemental application for a device that received Pre-Market Approval (PMA) or a new 510(k) is not required for a change to a device that would otherwise require a PMA supplement or a new 510(k) if the change is consistent with a PCCP approved or cleared by FDA. This final guidance is specific to AI-enabled devices, although PCCPs may be submitted for devices other than AI-enabled devices, and FDA has issued draft guidance that applies more broadly to all devices.

Categories

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